

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 12, 2007

MEMORANDUM

SUBJECT: Review of "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press*"

FROM: Charles Smith, Environmental Scientist/Risk Assessor
Reregistration Branch 2
Health Effects Division (7509P)

[Signature] 9/12/07

THRU: Jeff Evans, Biologist
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Health Effects Division (7509P)

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TO: Cathryn O'Connell
Special Review and Reregistration Division (7508P)

DP Barcode: 336767

PC Code: 109701 and 067501

MRID Number: 461886-25

Attached is a review of the MRID 461886-25 "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press*" submitted by the Non-Dietary Exposure Task Force. The purpose of the study was twofold. The first objective was to determine the amount of permethrin (PER) and piperonyl butoxide (PBO) residue transferred from treated vinyl and carpet flooring to bare and gloved adult hands utilizing a single hand press collection technique. The second objective was to compare the degree of residue transferred via two sampling strategies, i.e., (1) transfer from the single hand press technique versus (2) transfer to cotton percale cloth using the modified California indoor roller method.

The test formulation contained a target weight percentage of 0.77% permethrin (PER) (wt/wt) and 0.77% piperonyl butoxide (PBO) (wt/wt). It was applied via a sprayboom that was meant to simulate the use of a ready-to-use fogger. The desired deposition rate of the test material onto

the flooring samples was $3.96 \mu\text{g}/\text{cm}^2$ for both PER and PBO. Total deposition was monitored using alpha cellulose deposition coupons measuring $7.6 \text{ cm} \times 7.6 \text{ cm}$ placed at various randomly selected locations on the platforms.

The alpha cellulose deposition coupons placed on flooring sections used for vinyl roller sampling demonstrated an achieved deposition rate of 114% and 98% of the target rate for PER and PBO, respectively. The measured deposition was $4.51 \mu\text{g}/\text{cm}^2$ for PER and $3.87 \mu\text{g}/\text{cm}^2$ for PBO. Versar corrected the PBO residues for a field fortification recovery of 87%. Corrected PBO deposition rate was $4.45 \mu\text{g}/\text{cm}^2$, corresponding to 112% of target deposition.

The alpha cellulose deposition coupons placed on flooring used for the carpet roller sampling demonstrated an achieved deposition of 116% of the target deposition rate for PER and 104% of the target rate for PBO. The measured deposition rate was $4.61 \mu\text{g}/\text{cm}^2$ for PER and $4.13 \mu\text{g}/\text{cm}^2$ for PBO. After correction for a field recovery of 87% for PBO residues the calculated percentage of target deposition was 120% for PBO and the mean deposition was $4.75 \mu\text{g}/\text{cm}^2$.

Alpha cellulose deposition coupons placed on treated vinyl flooring sections which were used for hand press sampling achieved a deposition rate of 130% and 120% of the target rate for PER and PBO, respectively. Residue levels of $5.13 \mu\text{g}/\text{cm}^2$ PER and $4.75 \mu\text{g}/\text{cm}^2$ PBO were measured on the deposition coupons. After correction of PBO residue for low field fortification recovery, Versar calculated a residue level of $5.46 \mu\text{g}/\text{cm}^2$ PBO resulting in a deposition rate of 138% of target rate.

Alpha cellulose deposition on treated carpet flooring sections used for hand press sampling showed that the percent of target deposition rate actually deposited was 126% for PER and 113% for PBO. Residue levels of $5.00 \mu\text{g}/\text{cm}^2$ PER and $4.49 \mu\text{g}/\text{cm}^2$ PBO were measured on the alpha cellulose coupons. After correction for field fortification recovery, Versar found a residue level of $5.16 \mu\text{g}/\text{cm}^2$ PBO, resulting in deposition of 130% of the target rate.

Residues found on percale samples generated from the indoor roller sampling on vinyl treated flooring surface demonstrated PER residues averaging $0.066 \pm 0.030 \mu\text{g}/\text{cm}^2$. This equated to a calculated mean transferability of 1.45%. PBO residues sampled under the same circumstances averaged $0.022 \pm 0.005 \mu\text{g}/\text{cm}^2$ with a mean transferability of 0.57%. For carpet treated flooring surfaces using the indoor roller method, PER and PBO residues measured $0.202 \pm 0.022 \mu\text{g}/\text{cm}^2$ and $0.170 \pm 0.026 \mu\text{g}/\text{cm}^2$, respectively on the percale cloth. Mean transferability was 4.37% for PER and 4.13% for PBO. The calculation of mean transferability is dependent upon the achieved deposition on the treated surface of concern, which was measured with alpha cellulose deposition coupons. Versar corrected the achieved PBO deposition rate values for an 87% field fortification found on the alpha cellulose deposition coupons. When taking into account the corrected achieved deposition rate for PBO residues, the percent transferability of PBO residue was 0.50% for treated vinyl flooring surfaces, and 3.59% for treated carpet flooring surfaces. The findings illustrate that the percentage of PBO and PER residue transferred from carpet flooring sections to percale was higher than the percentage transferred from vinyl flooring sections. Also, the percentage of PBO transferred from vinyl to percale was less than half the percentage of PER transferred, while for carpet flooring surfaces, the percentage of PBO and PER transferred was similar.

Cotton glove residues transferred from treated vinyl flooring hand press samples averaged $0.041 \pm 0.022 \mu\text{g}/\text{cm}^2$ of palmar surface area for PER and $0.021 \pm 0.014 \mu\text{g}/\text{cm}^2$ for PBO. The percent of residue transferred from the treated vinyl flooring to the cotton glove was calculated as the ratio of the amount of residue present on the glove divided by the average residue deposited on the alpha cellulose coupons (i.e., $5.13 \mu\text{g}/\text{cm}^2$ for PER and $4.75 \mu\text{g}/\text{cm}^2$ for PBO). The study author reports that approximately 0.81% of PER residues and 0.45% of PBO residues were transferred to gloved hands from the vinyl flooring. Calculations made using Versar's corrected achieved deposition value for PBO (i.e., $5.46 \mu\text{g}/\text{cm}^2$ for PBO) yielded a transferability of 0.39% for PBO residues.

The mean residue transferred from treated vinyl flooring sections to the bare hand was $0.168 \pm 0.059 \mu\text{g}/\text{cm}^2$ of palmar surface area for PER and $0.105 \pm 0.035 \mu\text{g}/\text{cm}^2$ for PBO. This represented a mean transferability of 3.27% for PER and 2.21% for PBO. Calculations made using Versar's corrected deposition value for PBO yielded a transferability of 1.92% for PBO residues. For treated vinyl surfaces, the percent of PER transferred to the percale, gloved or bare hands was always higher than the percent of PBO transferred.

After a single hand press sampling event on carpet treated flooring sections, the residue transferred onto the cotton glove samples averaged $0.133 \pm 0.032 \mu\text{g}/\text{cm}^2$ of palmar surface area for PER and $0.124 \pm 0.031 \mu\text{g}/\text{cm}^2$ for PBO. The percent of residue transferred from the treated carpet flooring to the cotton glove was calculated as the ratio of the amount of residue present on the glove divided by the average residue deposited on the alpha cellulose coupons (i.e., $5.00 \mu\text{g}/\text{cm}^2$ for PER and $4.49 \mu\text{g}/\text{cm}^2$ for PBO). Approximately 2.66% of PER residues and 2.76% of PBO residues were transferred to gloved hands from the carpet flooring. Calculations made using Versar's corrected deposition value for PBO (i.e., $5.16 \mu\text{g}/\text{cm}^2$ for PBO) yielded a transferability of 2.40% for PBO residues.

Residues transferred from carpet flooring to the bare hand averaged $0.099 \pm 0.036 \mu\text{g}/\text{cm}^2$ for PER and $0.107 \pm 0.043 \mu\text{g}/\text{cm}^2$ for PBO. Approximately 1.98% of PER residues and 2.39% of PBO residues were transferred to bare hands from the carpet flooring. Calculations made using Versar's corrected achieved deposition value for PBO yielded a transferability of 2.08% for PBO residues. For carpet treated samples, the percent of PER and PBO residues transferred onto bare or gloved hands, are similar.

The primary review for this study was conducted by Versar, Inc. A secondary review was conducted by the Health Effects Division (HED). The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, both the performance of this study and the data generated in this study conformed to the criteria set forth in the protocol and guidelines. HED believes the data within this study is of high quality and valid for risk assessment purposes.



MEMORANDUM

TO: Margarita Collantes cc: 110082.4000.001.01
FROM: Susan Anderson/Linda Phillips
DATE: March 23, 2004
SUBJECT: Review of "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press*" (Project #: 00-017-PY01)

This report reviews a study entitled "*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press.*" The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study.

STUDY TYPE: Active Transfer; Vinyl and Carpet

TEST MATERIAL: Permethrin and Piperonyl Butoxide; pre-fill batch formulation (similar to that for an indoor fogger formulation)

SYNONYMS: Permethrin (PER) and Piperonyl Butoxide (PBO)

CITATION:

Author(s):	Sami Selim, Ph.D.
Study Director(s):	Sami Selim, Ph.D.
Title:	<i>Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press</i>
Study Completion Date:	October 01, 2003
Testing Facility:	Toxcon Health Sciences Research Centre Inc. 9607 - 41 st Avenue Edmonton, Alberta Canada T6E 5X7
Analytical Facility:	En-CAS Analytical Laboratories 2359 Farrington Point Drive Winston-Salem, North Carolina 27107 USA
Identifying Codes:	Toxcon Study No.: 01-017-PY01 EN-CAS Project No.: 01-0034

SPONSOR: Non-Dietary Exposure Task Force

EXECUTIVE SUMMARY:

This report reviews “*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press*” submitted by the Non-Dietary Exposure Task Force. The purpose of the study was twofold. The first objective was to determine the amount of permethrin (PER) and piperonyl butoxide (PBO) residue transferred from treated vinyl and carpet flooring to bare and gloved adult hands utilizing a single hand press collection technique. The second objective was to compare the degree of residue transferred via two sampling strategies, i.e., (1) transfer from the single hand press technique versus (2) transfer to cotton percale cloth using the modified California indoor roller method.

A sprayboom designed to simulate fogger spray was used to apply the test formulation containing a target weight percentage of 0.77% permethrin (PER) (wt/wt) and 0.77% piperonyl butoxide (PBO) (wt/wt). The formulation was applied in a test room in which vinyl and carpet flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of six 40" x 40" square wooden platforms. One sprayboom run per flooring surface was performed on two separate days. The desired deposition rate of the test material onto the flooring samples was 3.96 $\mu\text{g}/\text{cm}^2$ for both PER and PBO. Total deposition was monitored using alpha cellulose deposition coupons measuring 7.6 cm x 7.6 cm placed at various randomly selected locations on the platforms. PER and PBO residue levels were determined on the following sample matrices: percale coupons, alpha cellulose deposition coupons, bare hand press dressing sponges and cotton gloves. Five adult study subjects participated in the hand press experiments. The degree of transfer of PER and PBO residue from formulation-treated vinyl and carpet flooring sections to hands (bare and gloved) was examined by measurement of residues on the right and left hands of the study participants. Each test subject performed four hand press events (i.e., bare and gloved hand press with right hand and bare and gloved hand press with left hand) on sections of treated vinyl flooring and two days later performed four hand press events on sections of treated carpet flooring. Each hand press event involved a new treated segment of flooring. The hand palmar surface area of each subject was computer-generated using a scanned digital image of inked palm

prints. All subjects completed the study with no adverse events observed or reported. Additionally, weighted indoor roller sampling was conducted on four sections of treated vinyl flooring and two days later on four sections of treated carpet flooring. Residue transfer was measured using cotton percale coupons. Test samples were collected approximately 3.5 hours following application to simulate actual field use of the product. The ventilation system in the test room was turned off prior to application. Approximately 3 hours after test substance application the ventilation (i.e., damper) was turned back on and a 30 minute drying period followed. Samples were then collected.

The alpha cellulose deposition coupons placed on flooring sections used for vinyl roller sampling demonstrated an achieved deposition rate of 114% and 98% of the target rate for PER and PBO, respectively. The measured deposition was $4.51 \mu\text{g}/\text{cm}^2$ for PER and $3.87 \mu\text{g}/\text{cm}^2$ for PBO. Versar corrected the PBO residues for a field fortification recovery of 87%. Corrected PBO deposition rate was $4.45 \mu\text{g}/\text{cm}^2$, corresponding to 112% of target deposition.

The alpha cellulose deposition coupons placed on flooring used for the carpet roller sampling demonstrated an achieved deposition of 116% of the target deposition rate for PER and 104% of the target rate for PBO. The measured deposition rate was $4.61 \mu\text{g}/\text{cm}^2$ for PER and $4.13 \mu\text{g}/\text{cm}^2$ for PBO. After correction for a field recovery of 87% for PBO residues the calculated percentage of target deposition was 120% for PBO and the mean deposition was $4.75 \mu\text{g}/\text{cm}^2$.

Alpha cellulose deposition coupons placed on treated vinyl flooring sections which were used for hand press sampling achieved a deposition rate of 130% and 120% of the target rate for PER and PBO, respectively. Residue levels of $5.13 \mu\text{g}/\text{cm}^2$ PER and $4.75 \mu\text{g}/\text{cm}^2$ PBO were measured on the deposition coupons. After correction of PBO residue for low field fortification recovery, Versar calculated a residue level of $5.46 \mu\text{g}/\text{cm}^2$ PBO resulting in a deposition rate of 138% of target rate.

Alpha cellulose deposition on treated carpet flooring sections used for hand press sampling showed that the percent of target deposition rate actually deposited was 126% for PER and 113% for PBO. Residue levels of $5.00 \mu\text{g}/\text{cm}^2$ PER and $4.49 \mu\text{g}/\text{cm}^2$ PBO were measured on the alpha cellulose coupons. After correction for field fortification recovery, Versar found a residue level of $5.16 \mu\text{g}/\text{cm}^2$ PBO, resulting in deposition of 130% of the target rate.

Residues found on percale samples generated from the indoor roller sampling on vinyl treated flooring surface demonstrated PER residues averaging $0.066 \pm 0.030 \mu\text{g}/\text{cm}^2$. This equated to a calculated mean transferability of 1.45%. PBO residues sampled under the same circumstances averaged $0.022 \pm 0.005 \mu\text{g}/\text{cm}^2$ with a mean transferability of 0.57%. For carpet treated flooring surfaces using the indoor roller method, PER and PBO residues measured $0.202 \pm 0.022 \mu\text{g}/\text{cm}^2$ and $0.170 \pm 0.026 \mu\text{g}/\text{cm}^2$, respectively on the percale cloth. Mean transferability was 4.37% for PER and 4.13% for PBO. The calculation of mean transferability is dependent upon the achieved deposition on the treated surface of concern, which was measured with alpha cellulose deposition coupons. Versar corrected the achieved PBO deposition rate values for an 87% field fortification found on the alpha cellulose deposition coupons. When taking into account the corrected achieved deposition rate for PBO residues, the percent transferability of PBO residue was 0.50% for treated vinyl flooring surfaces, and 3.59% for treated carpet flooring surfaces. The findings illustrate that the percentage of PBO and PER residue transferred from carpet flooring sections to percale was higher than the percentage transferred from vinyl flooring sections. Also, the percentage of PBO transferred from vinyl to percale was less than half the percentage of PER transferred, while for carpet flooring surfaces, the percentage of PBO and PER transferred was similar.

Cotton glove residues transferred from treated vinyl flooring hand press samples averaged $0.041 \pm 0.022 \mu\text{g}/\text{cm}^2$ of palmar surface area for PER and $0.021 \pm 0.014 \mu\text{g}/\text{cm}^2$ for PBO. The percent of residue transferred from the treated vinyl flooring to the cotton glove was calculated as the ratio of the amount of residue present on the glove divided by the average residue deposited on the alpha cellulose coupons (i.e., $5.13 \mu\text{g}/\text{cm}^2$ for PER and $4.75 \mu\text{g}/\text{cm}^2$ for PBO). The study author reports that approximately 0.81% of PER residues and 0.45% of PBO residues were transferred to gloved hands from the vinyl flooring. Calculations made using Versar's corrected achieved deposition value for PBO (i.e., $5.46 \mu\text{g}/\text{cm}^2$ for PBO) yielded a transferability of 0.39% for PBO residues.

The mean residue transferred from treated vinyl flooring sections to the bare hand was $0.168 \pm 0.059 \mu\text{g}/\text{cm}^2$ of palmar surface area for PER and $0.105 \pm 0.035 \mu\text{g}/\text{cm}^2$ for PBO. This represented a mean transferability of 3.27% for PER and 2.21% for PBO. Calculations made using Versar's corrected deposition value for PBO yielded a

transferability of 1.92% for PBO residues. For treated vinyl surfaces, the percent of PER transferred to the percale, gloved or bare hands was always higher than the percent of PBO transferred.

After a single hand press sampling event on carpet treated flooring sections, the residue transferred onto the cotton glove samples averaged $0.133 \pm 0.032 \mu\text{g}/\text{cm}^2$ of palmar surface area for PER and $0.124 \pm 0.031 \mu\text{g}/\text{cm}^2$ for PBO. The percent of residue transferred from the treated carpet flooring to the cotton glove was calculated as the ratio of the amount of residue present on the glove divided by the average residue deposited on the alpha cellulose coupons (i.e., $5.00 \mu\text{g}/\text{cm}^2$ for PER and $4.49 \mu\text{g}/\text{cm}^2$ for PBO). Approximately 2.66% of PER residues and 2.76% of PBO residues were transferred to gloved hands from the carpet flooring. Calculations made using Versar's corrected deposition value for PBO (i.e., $5.16 \mu\text{g}/\text{cm}^2$ for PBO) yielded a transferability of 2.40% for PBO residues.

Residues transferred from carpet flooring to the bare hand averaged $0.099 \pm 0.036 \mu\text{g}/\text{cm}^2$ for PER and $0.107 \pm 0.043 \mu\text{g}/\text{cm}^2$ for PBO. Approximately 1.98% of PER residues and 2.39% of PBO residues were transferred to bare hands from the carpet flooring. Calculations made using Versar's corrected achieved deposition value for PBO yielded a transferability of 2.08% for PBO residues. For carpet treated samples, the percent of PER and PBO residues transferred onto bare or gloved hands, are similar.

Table 9 summarizes the mean transferability of PER and PBO residue from treated vinyl and carpet flooring sections to the indoor roller percale cloth, and to bare and gloved hands. The results suggest that after contact with vinyl treated flooring surfaces, the percent of PER transferred to percale, and gloved or bare hands is always higher than the percent of PBO residue transferred. Also for vinyl surfaces, the percent of PER and PBO transferred to the bare hand was higher than the percent transferred to the gloved hand or to percale. The percentage of deposited PER and PBO residue transferred from vinyl treated flooring to percale and gloved hands was lower than the percentages observed after contact with carpet treated flooring.

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
- The test product was not identified and a label was not provided.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The study author did not correct the PBO residue data on alpha cellulose deposition coupons for the field fortification recovery, which was below 90%.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP) and Data Confidentiality statements and a summary of the Quality Assurance inspection dates and report dates were provided. The Study Report noted that the study was performed according to the U.S. EPA FIFRA Good Laboratory Practice Regulations currently in effect (40 CFR, Part 160), with the following exceptions: (1) conventional and digital photography used in the report was not done according to GLP Regulations and the resulting photographs are to be considered as non-GLP, (2) digital images of hand palmar surface scans and computerized method of calculating surface area was not done according to GLP Regulations and (3) information recorded on subject entry, exit and hand inspection forms was not entered and/or corrected according to GLP Regulations. A Quality Assurance statement was provided in the EN-CAS Analytical Laboratories Analytical Phase Report.

GUIDELINE OR PROTOCOL FOLLOWED:

The study was conducted following Toxcon and EN-CAS Standard Operating Procedures and the protocol of the Non-Dietary Exposure Task Force (Toxcon Protocol No. 01-017-PY01).

I. MATERIALS AND METHODS

A. Materials:

1. Test Material:

Formulation:	An unidentified pre-fill formulation similar to that for an indoor fogger; developed by McLaughlin Gormley King Company (MGK); containing a target weight percentage of 0.77% permethrin (PER) (wt/wt) and 0.77% piperonyl butoxide (PBO) (wt/wt)
Batch # Formulation:	0109-1, 0109-2
Formulation Guarantee:	MGK Certificate of Analysis stated that the test substance contained 0.773% PER and 0.748% PBO for batch 0109-1 and 0.771% PER and 0.741% PBO for batch 0109-2. The analyses were dated September 26, 2001 and 7/10/03.
CAS #(s):	Permethrin: 52645-53-1 Piperonyl butoxide: 51-03-6
Other Relevant Information:	Toxcon ID No.: PY01T009, manufactured by MGK

2. Relevance of Test Material to Proposed Formulation(s):

Permethrin and piperonyl butoxide are active ingredients in formulated consumer products intended for use in residential dwellings. The product used was a pre-fill batch formulation similar to that of an indoor fogger formulation developed by MGK. The name and label for the test product was not provided with the study.

B. Study Design:

The study followed the proposed study protocol but required four amendments and the study reported one protocol deviation. The Study Report stated that none of the amendments would be expected to impact the study. Amendment 1 involved the substitution of the more absorbent 6-ply dressing sponges for the proposed 8-ply gauze sponges used for removing residue from test subjects' hands. The dressing sponges retained the isopropyl alcohol better during hand wiping, possibly affecting the removal efficiency. Amendment 2 involved the change in the Analytical Principal Investigator and correction of an editing and a typographical error. Amendment 3 allowed for the addition of flooring specifications for carpet to the Study Report. Amendment 4 noted a change in responsibilities requiring a name change of the sponsor representative and submitter for the Non-dietary Exposure Task Force. The following protocol deviations were reported: (1) field spike levels for alpha cellulose, glove, hand wipe and percale samples were adjusted from the protocol specified levels to reflect spike values closer to the values expected in actual samples and (2) as is standard practice at Toxcon, micropipettes were used for preparation of field-fortification samples rather than a syringe. The Study Report states that these deviations were not expected to have an adverse impact on the study.

1. Site Description:

Test Locations: The test site was located at the Toxcon Health Sciences Research Centre in Canada. Three test rooms (Simulated Residential Rooms (SRRs)) were used. One contained the application equipment (the sprayboom). The rooms were prepared according to Toxcon SOP No. E-025: *Preparation of Test Rooms Prior to an Experiment* and M-026: *Masking of the Test Room and the Sprayboom Prior to an Experiment*.

Meteorological Data: Target test room conditions prior to application included an air exchange rate of 0.6 ± 0.1 air changes per hour (ACH), a temperature of $72 \pm 4^{\circ}\text{F}$ and a relative humidity of $50 \pm 10\%$.

Ventilation/Air-Filtration: The ventilation system for the application room was turned off (dampers closed) during application and for three hours after application. The dampers were opened after the three hours and the room conditions were adjusted to reach the conditions prior to application for a 30 minute drying period.

2. Surface(s) Monitored:

- Room(s) Monitored: Three test rooms (SRRs) were used. The sprayboom room contained alpha cellulose deposition coupons and vinyl and carpet flooring sections on plastic sheeting covered wooden platforms. A second room was used to perform the hand press procedures and the third room was used for preparation of the field quality control samples.
- Room Size(s): Room dimensions of each SRR were 16 ft x 16 ft x 8 ft. Six wooden platforms (40" x 40" each) were placed in the center of the spray room.
- Types of Surface(s): Carpet and vinyl flooring
- Surface Characteristics: Vinyl and carpet flooring sections were pinned onto a sheet of plastic-covered plywood attached to the top of the wooden platforms measuring 40" x 40" each. The carpet and vinyl flooring specifications were provided in the Study Report. The vinyl flooring was made by DOMCO Inc. and featured a no-wax vinyl finish. The carpet was manufactured by KRAUS with the product name "Hyde Park." The carpet was made of saxony cut pile (100% BCF nylon) and was pre-treated with Master Guard™. Prior to application of the test substance using the sprayboom apparatus equipment, the platforms were rolled together and placed in the center of the room.
- Areas Sprayed and Sampled: Enough treated vinyl and carpet flooring sections were generated from the run to perform the bare and gloved hand press experiments on five subjects as well as the roller procedure. A layout diagram for deposition coupons, vinyl or carpet flooring sections and roller samples was provided on page 108 of the Study Report. Vinyl or carpet flooring sections, cut into 12" x 8" sections, were pinned onto sheets of plastic-covered plywood attached to the top of three wooden platforms. Two of the wooden platforms were covered in the same manner for the roller testing. These platforms were divided into testing lanes measuring 40" x 16". A sixth platform was not sampled, but was treated.
- Other Products Used: N/A

3. Physical State of Formulation as Applied : Fogger

4. Application Rates and Regimes:

- Application Equipment: Sprayboom designed to simulate a fogger spray
- Application Regime: One sprayboom run was performed on two separate days, one run for vinyl flooring and one run for carpet flooring.
- Application Rate(s): The actual application rate used in the experiments was not provided in the Study Report. Application was based on the desired deposition rate of $3.96 \mu\text{g}/\text{cm}^2$ PER (~0.77% wt/wt) and $3.96 \mu\text{g}/\text{cm}^2$ PBO (~0.77% wt/wt) onto vinyl and carpet flooring surfaces. The desired deposition rates were based on results of indoor PER and PBO-based total release fogger deposition studies. The sprayboom nozzle sweep speed required to obtain the desired deposition was calculated using the following equation: $U = [(Q_t)(F_a)(k_1)/(R)(n)(d)(10^{-6})]$, where U is the sprayboom nozzle sweep speed (cm/s), Q_t is the nozzle output rate (g/s), F_a is the fraction of PER in the formulation, R is the target deposition rate of PER ($\mu\text{g}/\text{cm}^2$), d is a fixed value representing the distance between nozzles (71.2 cm), n is the number of nozzles (5), and k_1 is a correction factor to account for formulation that is sprayed, but not deposited, on the test surface. The target speed was not provided in the Study Report but was reported to be documented in the raw data.

Equipment Calibration Procedures: The Study Report states that a calibrated sprayboom was used in the study, but calibration procedures were not provided. It is not certain if the equipment used in this study was consistent with the proposed use for this product. The label recommended application method/rate could not be determined because a label was not provided with the study.

Was Total Deposition Measured: Total deposition was measured using deposition coupons. The deposition coupons consisted of squares of alpha cellulose (approximately 3" x 3"). The coupons were backed with hexane-wiped heavy duty aluminum foil. The Study Report states that coupons were prepared according to Toxcon SOP No. M-015: *Preparation of Alpha Cellulose Deposition Coupon*. The coupons were present on the wooden platforms during test substance application.

D. Sampling:

Surface Areas Sampled: Treated vinyl and carpet flooring sections present on wooden platforms in a SRR.

Replicates per Sampling Interval: Both gloved and bare hand press samples were collected. Samples were taken from left and right hand presses of each of the 5 study participants. One sampling interval consisted of collection of 10 gloved and 10 bare-hand presses on vinyl flooring sections. At a different sampling event the same 5 subjects performed 10 gloved and 10 bare hand presses on carpet flooring sections. The indoor roller sampling events produced 4 roller samples for each flooring type.

Number of Sampling Intervals: Vinyl flooring samples were collected during one sampling interval and carpet flooring samples were collected during a different sampling interval.

Method and Equipment: Residue deposition was measured with alpha cellulose deposition coupons. Residue transfer was determined using bare hand and gloved hand presses and the modified indoor roller technique fitted with cotton percale cloth.

Sampling Procedure(s) :

Deposition coupons - Alpha cellulose deposition coupons were randomly placed on the surfaces to be treated, prior to test substance application. They were collected following a drying period after application of the test material. Disposable latex gloves were worn when coupons were handled. The coupons were folded, so that the exposed side was on the inside, and then wrapped in hexane-wiped aluminum foil.

Dressing sponge residues - After application of the test substance, and following collection of the deposition coupons, the treated flooring sections were removed from 3 of the 6 platforms and moved to a hand press room. Approximately 3.5 hours after application of the test substance, sections of flooring was placed on a hand press balance in a random sequence. Each test washed and dried their hands before placing the palm (not fingers) of one hand on the balance at a force of approximately 8 kg for approximately 20 seconds. Immediately following the hand press procedure, transferred residue was collected using an isopropyl alcohol (IPA) double wipe procedure. The palm was wiped with two 4" x 4" 6-ply dressing sponges. The wipes were pre-moistened with approximately 5 mL of IPA prior to its use. The hand wipes were placed in separate amber glass jars with teflon-lined lids. The flooring section was changed, and the subject repeated the process with the other hand.

Cotton glove residues - Subjects placed a thin, 100 percent cotton glove on their hands and performed the hand press procedure previously described with their gloved hands. Previously unsampled, treated flooring sections were used for each new hand press collection. Laboratory personnel removed each subject's glove and placed the glove in an amber glass jar with a teflon-lined lid.

Palmar surface area - Hand palmar surface areas were determined using an ink image of the palm side of each hand, which was then scanned into a computer to create a digital image of the hand. This is consistent with the procedure

described in Toxcon SOP's Nos. M-021 and M-022. The computerized method of calculating surface area is described in Toxcon SOP No. M-010. The hand palmar surface area was measured for each study participant.

Percal cloth residues - After application of the test substance, and following removal of the deposition coupons, the indoor roller assembly was fitted to test lanes on 2 of the 6 platforms and testing was performed. After each use of the indoor roller the frame assembly was carefully washed and refitted for the next sampling event. Cotton percale cloth was used as the test surface material for the dosimeter. The percale dosimeter and quality control coupons were prepared according to Toxcon SOP No. M-018. The design and use of the indoor roller is described in Toxcon SOP No. M-011. The Study Report does not provide detail on the sampling procedure.

3. Sample Handling and Storage:

Dressing sponges and cotton gloves collected from the hand press procedures were placed in separate pre-labeled 180 mL amber glass jars with Teflon-lined lids. Deposition coupons were placed in aluminum containers and moved to freezer storage (<-5°C) within 3 hours of collection. All samples were stored at <-5°C until shipment for analysis. Samples were shipped to the analytical laboratory overnight in an insulated cooler with dry ice. Samples were stored and shipped according to Toxcon SOP Nos. G-022, *Storage of Test Samples and Analytical Extracts* and G-028 *Test Sample Distribution to a Contract Laboratory*, respectively. Samples were received at the analytical laboratory in frozen condition and were transferred to freezer storage and maintained at <-10°C until analysis.

IV. ANALYTICAL METHODOLOGIES

A. Extraction Method:

Percal roller coupons, deposition coupons, and cotton gloves: Extraction was performed by mechanical shaking of the sample matrix with 90/10 hexane/acetone. Aliquots of extracts not requiring concentration were mixed with 0.05% dimethyldichlorosilane (DMDCS) in hexanes. Samples requiring concentration, were taken to dryness using an N-evap and then reconstituted in acetonitrile.

Dressing sponges: Extraction was performed by mechanical shaking of the dressing sponges at room temperature with 70/30 hexanes/acetone. Low level field and laboratory QC samples required evaporative concentration and reconstituted with acetonitrile. A 1.0 mL aliquot of extract, or the appropriate dilution or concentration, was mixed with 10 mL of 0.05% dimethyldichlorosilane (DMDCS) in hexanes prior to GC injection.

B. Detection Methods:

Table 1 summarizes the gas chromatographic (GC) and high performance liquid chromatographic (HPLC) settings used to analyse PER and PBO residues found on the sample matrices. Initial GC mass spectrophotometric detector (MSD) analysis of test samples revealed that LOQ level laboratory fortification recoveries for PBO began to reflect enhancement due to the effect of repetitive injections of concentrated matrix upon the GC/MSD. An alternate HPLC system utilizing a fluorescence detector (FD) procedure was developed for the PBO analysis of all concentrated extracts. The HPLC/FD system for PBO was used to quantitate field fortification and blank samples if the expected residue level indicated that the samples would require concentration to fall within the calibration curve range. All QC samples fortified at levels other than LOQ were assayed by GC/MSD. For dressing sponge samples requiring concentration, PBO results were obtained using the HPLC/FD system. No actual study samples required concentration, and therefore all PBO study sample analyses were conducted using GC/MSD.

Gas chromatographic separation of the two isomers (cis and trans) of PER was achieved with the use of a DB-5 column. The two isomer peaks were detected by electron capture device (ECD), summed and quantitated on one calibration curve.

Table 1. Gas Chromatographic and HPLC Conditions	
Gas Chromatographic Conditions	
GC Column	DB-5 column with ECD or a DB-1 column with MSD
Temperatures	not reported
Carrier Gas Flow Rate	not reported
Injection Volume	1 μ L
Injection Rate	not reported
Approximate Retention Times	PER cis isomer ~ 11.6 minutes PER trans isomer ~ 12.0 minutes PBO ~ 8.8 minutes Retention time was delayed on cotton glove matrix samples (e.g., approximately 13.8 minutes for cis isomer of PER and 14.3 minutes for corresponding trans isomer)
Liquid Chromatographic Conditions	
Column	Zorbax SB-C18 fitted with a Zorbax phenyl pre-column programmed to transfer only the pre-column eluant in the PBO retention time region to the Zorbax SB-C18 column ^a
Temperature	not reported
Mobile Phase	60% acetonitrile 40% water in the pre-column and 80% acetonitrile 20% water used in the C18 column
Flow Rate	not reported
Injection Volume	not reported
Fluorescence Detection	Excitation: 288 nm Emission: 345 nm
Approximate Retention Time	PBO: ~ 8.0 min

a An exception to this setup was a group of low-level dressing sponge field fortifications which were analyzed using the Zorbax SB-C18 column alone and an eluant of 70/30 acetonitrile/water.

C. Method Validation:

The determination of PER and PBO on cotton gloves, percale coupons, and alpha cellulose deposition coupons was performed using the validated EN-CAS Analytical Method No. ENC-1/01 "Analytical Method for the Determination of Permethrin (PER) and Piperonyl Butoxide (PBO) in/on Various Indoor Exposure Study Matrices, Rev.1". Residues from bare hand press samples, which used IPA-moistened dressing sponges to remove residues, were analyzed using the validated EN-CAS Analytical Method No. ENC-2/01 "Analytical Method for the Determination of Permethrin (PER) and Piperonyl Butoxide (PBO) in/on Isopropanol-Moistened Dressing Sponges". The Study Report states that the limits of quantitation (LOQs) are based upon the lower limit of method validation. The matrix specific LOQs are reported for PER and PBO in Table 2.

Table 2. Validated LOQs		
Matrix	PER	PBO
Alpha Cellulose Deposition Coupon	10.0 μ g or 0.173 μ g/cm ²	8.66 μ g or 0.150 μ g/cm ²
Cotton Percale Coupon	0.100 μ g or 0.0008 μ g/cm ²	0.0866 μ g 0.00069 μ g/cm ²
Dressing Sponges	0.200 μ g	0.173 μ g
Cotton Gloves	0.200 μ g	0.173 μ g

Instrument performance and calibration:

Calibration solutions were prepared from stock solutions by dilution with 90:10 hexanes:acetone. A total of 5 concentrations were used to calibrate the system: 0.005, 0.01, 0.02, 0.05, and 0.10 μ g/mL. The GC/MS response was determined using the prepared calibration standards to perform a linear regression analysis. PBO standards for

the HPLC/FD analyses were prepared using the diluent described above to make dilutions down to 0.0025 µg/mL.

D. Quality Control:

Alpha Cellulose Coupons: Two types of foil backed alpha cellulose coupons measuring approximately 3 inches square (7.6 cm x 7.6 cm), were used in this study: (1) deposition coupons and (2) quality control coupons. Deposition coupons present on the platforms during test substance application were used to measure deposition of formulation onto the vinyl and carpet flooring surfaces. Quality control coupons were prepared by the analytical laboratory for use in each deposition sample run. Collection of the deposition coupons required handling with latex gloves. Each coupon was folded on a clean surface, with the exposed side on the inside, and wrapped with a piece of hexane-wiped aluminum foil, in order to prevent cross-contamination between samples. Samples were frozen within 3 hours of coupon retrieval.

Lab Recovery: To obtain recovery and method performance data, concurrent laboratory control samples were fortified with the formulated product, prior to extraction, within the concentration ranges expected from the field samples. According to the study protocol, average laboratory recoveries in the range of 70 to 120% with a coefficient of variation of +/- 25% were considered acceptable for the study. Results from the laboratory fortified samples are summarized in Table 3. Overall average recoveries were 98 ± 3.8% for PER and 94 ± 7.9% for PBO on alpha cellulose coupons. Cotton glove recoveries for PER averaged 104 ± 5.2% and 114 ± 14% for PBO overall. Overall average recoveries were 105 ± 9.1% for PER and 101 ± 8.8% for PBO on dressing sponges. Laboratory recoveries for percale coupons averaged 107 ± 11% for PER and 92 ± 20% for PBO. Coefficients of variation were with acceptable limits.

Table 3. Summary of Concurrent Laboratory Fortification Recoveries

Matrix	Fortification Level (µg)			No. Samples	Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
		PER	PBO		PER	PBO	PER	PBO	PER	PBO	PER	PBO
Alpha Cellulose Coupons	~LOQ	10	8.66	5	96	94	98	94	3.8	7.9	3.9	8.4
	~20x LOQ	200	173	3	101	96						
	~40x LOQ	400	346	1	102	98						
	~50x LOQ	500	433	1	95	87						
Cotton Gloves	~LOQ	0.2	0.173	3	107	107	104	114	5.2	14	5.0	12
	~50x LOQ	10	8.66	1	105	113						
	~250x LOQ	50	43.3	1	103	131						
	~500x LOQ	100	86.6	1	95	118						
Dressing Sponges	~LOQ	0.2	0.173	2	114	109	105	101	9.1	8.8	8.7	8.7
	~2x LOQ	0.4	0.346	1	108	109						
	~125x LOQ	25	21.7	1	106	94						
	~250x LOQ	50	43.3	1	94	94						
	~500x LOQ	100	86.6	1	95	92						
Percale Cloth	~LOQ	0.1	0.09	2	116	76	107	92	11	20	10	21
	~1000x LOQ	100	86.6	1	91	87						
	~6000x LOQ	600	520	1	112	121						
	~7000x LOQ	700	606	1	103	102						

Field Fortification: Six low level and three high level field fortification samples were prepared for each sample matrix. The dressing sponges field fortification samples were placed in amber glass jars with an addition of IPA and then spiked in the jars. The other matrices were placed on a clean dry surface during spiking. With the exception of percale, all the matrices were the same size as the field samples of that matrix. The percale fortified and blank samples were approximately one half the field sample size. The field fortified control samples were exposed for the same amount of time and under the same conditions as the test samples. They were also stored and analyzed with the test samples. Field fortification results are summarized in Table 4. The overall mean field fortification recoveries (i.e., mean of high and low fortified levels) for alpha cellulose coupons were $94\% \pm 8.0\%$ for PER and $87\% \pm 12.4\%$ for PBO. Cotton glove overall average recoveries were $101\% \pm 7.2\%$ for PER and $112\% \pm 15.6\%$ for PBO. The overall mean field fortification recoveries for dressing sponges were $105\% \pm 3.6\%$ for PER and $108\% \pm 14.5\%$ for PBO. Cotton percale overall average recoveries were $98\% \pm 6.2\%$ for PER and $94\% \pm 18.8\%$ for PBO.

Matrix	Fortification Level (µg)			n	Mean Residue (µg)		Percent Recovery (%)		Overall Average Recovery (%)		Std. Dev.		% RSD	
		PER	PBO		PER	PBO	PER	PBO	PER	PBO	PER	PBO	PER	PBO
Alpha Cellulose Coupons	~8x LOQ	75.3	67.5	6	75	63.3	100	94	94	87	8.0	12.4	8.5	14.4
	~40x LOQ	377	338	6	335	268	89	79						
Cotton Gloves	~4x LOQ	0.805	0.6	6	0.852	0.69	106	115	101	112	7.2	15.6	7.1	13.9
	~160x LOQ	31.5	27.5	6	30.1	30	96	109						
Dressing Sponges	~4x LOQ	0.805	0.6	6	0.847	0.7	105	116	105	108	3.6	14.5	3.4	13.5
	~160x LOQ	31.5	27.5	6	33.2	27.4	105	100						
Percale Cloth	~15x LOQ	15.7	13.7	6	15.8	14.8	100	108	98	94	6.2	18.8	6.3	19.9
	~650x LOQ	677	640	6	642	521	95	81						

n = number of samples

Control Samples: The field blank samples of each sample matrix were treated with the fortifying solvent but not formulation. The alpha cellulose and percale samples were folded with the exposed sides on the inside, wrapped in hexane-wiped foil, and then labeled. The hand wipe and glove samples were directly placed into 180 mL amber jars. No PER or PBO residue, at or above the LOQ was found in any of the non-fortified blank control samples.

Storage Stability: After collection, all samples were stored in the dark at less than -5°C until shipment for analysis. The samples were received by the analytical laboratory in frozen condition and transferred to freezer storage and stored at less than -10°C until analysis. Field fortifications and test samples were analyzed within 130 days of sample collection. While no actual storage stability study was conducted, the Study Report states that the recovery results for the field fortified samples confirmed the stability of the residues over the storage period.

V. RESULTS

Residues values were reported for both PER and PBO. Versar corrected appropriate residue data for field fortification recoveries below 90% (i.e., PBO residues on alpha cellulose deposition coupons). The Registrant did not correct for field fortification recoveries.

A. Alpha Cellulose and Deposition of Formulation:

Alpha cellulose deposition coupons were placed in a predetermined random pattern along the treated flooring sections on the test platforms and served to assess deposition of the test substance onto the treated surface. Results are reported for deposition onto the following treated surface types (1) vinyl flooring sampled using an indoor roller, (2) vinyl flooring sampled using a hand press, (3) carpet flooring sampled using an indoor roller and (4) carpet flooring sampled using a hand press. Table 5 contains a summary of the deposition coupon residues of PER and PBO found on surfaces designated for performance of the different sampling strategies.

Deposition on Vinyl Roller Surface: The alpha cellulose deposition coupons placed on flooring sections used for vinyl roller sampling demonstrated an achieved deposition rate of 114% of the target rate for PER and 98% of the target rate for PBO. The measured deposition was 4.51 $\mu\text{g}/\text{cm}^2$ for PER and 3.87 $\mu\text{g}/\text{cm}^2$ for PBO. Versar corrected the PBO residues for a field fortification recovery of 87%. Corrected PBO deposition rate was 4.45 $\mu\text{g}/\text{cm}^2$, corresponding to 112% of target deposition.

Deposition on Vinyl Hand Press Surface: Alpha cellulose deposition coupons placed on treated vinyl flooring sections which were used for hand press sampling achieved a deposition rate of 130% of the target rate for PER and 120% of the target rate for PBO. Residue levels of 5.13 $\mu\text{g}/\text{cm}^2$ PER and 4.75 $\mu\text{g}/\text{cm}^2$ PBO were measured on the deposition coupons. After correction of PBO residue for low field fortification recovery, Versar calculated a residue level of 5.46 $\mu\text{g}/\text{cm}^2$ PBO resulting in a deposition rate of 138% of target rate.

Deposition on Carpet Roller Surface: The alpha cellulose deposition coupons placed on flooring used for the carpet roller sampling demonstrated an achieved deposition of 116% of the target deposition rate for PER and 104% of the target rate for PBO. The measured deposition rate was 4.61 $\mu\text{g}/\text{cm}^2$ for PER and 4.13 $\mu\text{g}/\text{cm}^2$ for PBO. After correction for a field recovery of 87% for PBO residues, the calculated percentage of target deposition was 120% for PBO and the mean deposition was 4.75 $\mu\text{g}/\text{cm}^2$.

Deposition on Carpet Hand Press Surface: Alpha cellulose deposition on treated carpet flooring sections used for hand press sampling showed that the percent of target deposition rate actually deposited was 126% for PER and 113% for PBO. Residue levels of 5.00 $\mu\text{g}/\text{cm}^2$ PER and 4.49 $\mu\text{g}/\text{cm}^2$ PBO were measured on the alpha cellulose coupons. After correction for field fortification recovery, Versar found a residue level of 5.16 $\mu\text{g}/\text{cm}^2$ PBO, resulting in deposition of 130% of the target rate.

Table 5. Summary of Deposition onto Alpha Cellulose Deposition Sponges								
Study Segment	Deposition Rate ($\mu\text{g}/\text{cm}^2$) ^a			Coefficient of Variation (%)		% of Target Deposition Rate ^b		
	PER	PBO	Corrected PBO ^c	PER	PBO	PER	PBO	Corrected PBO ^c
Vinyl Hand Press	5.13	4.75	5.46	25	29	130	120	138
Vinyl Roller	4.51	3.87	4.45	27	27	114	98	112
Carpet Hand Press	5.00	4.49	5.16	14	16	126	113	130
Carpet Roller	4.61	4.13	4.75	20	22	116	104	120

a Deposition Rate ($\mu\text{g}/\text{cm}^2$) = residue on alpha cellulose coupon (μg) / surface area (57.76 cm^2)

b % of Target Deposition Rate = deposition on alpha cellulose coupon ($\mu\text{g}/\text{cm}^2$) / target deposition rate of $3.96 \text{ ug}/\text{cm}^2$

c Corrected PBO value ($\mu\text{g}/\text{cm}^2$) = reported residue value ($\mu\text{g}/\text{cm}^2$) / 0.87 field fortification recovery

B. Cotton Glove Residues

PBO and PER residue transferred onto gloved hands following a hand press event was estimated from analysis of thin cotton gloves worn by five individuals performing a right hand single hand press event and a left hand single hand press event while wearing a cotton glove on each hand. Twenty gloved hand press samples were collected; ten samples were collected from carpet flooring sampling, and ten looked at residue transfer from a hand press on vinyl flooring. Residue levels expressed as μg in the glove sample and as g/cm^2 of subject-specific palmar surface area are summarized in Tables 6 for vinyl flooring surfaces and Table 7 for carpet flooring surfaces. The percent transferability from the surfaces to the gloves is also summarized in the tables. The cotton glove residue data did not require correction for field fortification recoveries.

Glove Residue - Vinyl Flooring: Cotton glove residues transferred from treated vinyl flooring hand press sampling averaged $0.041 \pm 0.022 \text{ } \mu\text{g}/\text{cm}^2$ for PER and $0.021 \pm 0.014 \text{ } \mu\text{g}/\text{cm}^2$ for PBO. The percent of residue transferred from the treated vinyl flooring to the cotton glove was calculated as the ratio of the amount of residue present on the glove divided by the average corrected residue deposited on the alpha cellulose coupons (i.e., $5.13 \text{ } \mu\text{g}/\text{cm}^2$ for PER and $4.75 \text{ } \mu\text{g}/\text{cm}^2$ for PBO). The study author reports that approximately 0.81% of PER residues and 0.45% of PBO residues were transferred to gloved hands from the vinyl flooring. Using Versar's corrected deposition value for PBO (i.e., $5.46 \text{ } \mu\text{g}/\text{cm}^2$ for PBO) on alpha cellulose deposition coupons yielded a calculated mean transferability value of 0.39% for PBO residues.

Glove Residue - Carpet Flooring: After a single hand press on carpet, the residue transferred onto the cotton glove hand press samples averaged $0.133 \pm 0.032 \text{ } \mu\text{g}/\text{cm}^2$ for PER and $0.124 \pm 0.031 \text{ } \mu\text{g}/\text{cm}^2$ for PBO. The percent of residue transferred from the treated carpet flooring to the cotton glove was calculated as the ratio of the amount of residue present on the glove divided by the average corrected residue deposited on the alpha cellulose coupons (i.e., $5.00 \text{ } \mu\text{g}/\text{cm}^2$ for PER and $4.49 \text{ } \mu\text{g}/\text{cm}^2$ for PBO). Approximately 2.66% of PER residues and 2.76% of PBO residues were transferred to gloved hands from the carpet flooring. Calculations made using Versar's corrected deposition value for PBO (i.e., $5.16 \text{ } \mu\text{g}/\text{cm}^2$ for PBO) yielded a mean transferability of 2.40% for PBO residues.

C. Dressing Sponges

PBO and PER residue transfer onto the palm of bare hands after a hand press event was estimated from analysis of hand wipe dressing sponges collected from five individuals performing a right hand single hand press event and a left hand single hand press event. Twenty dressing sponge hand press samples (representing bare hand transfer) were collected in total; ten samples were collected from carpet flooring sampling, and ten looked at residue transfer from vinyl flooring samples. The residue expressed as g in the dressing sponges and as $\mu\text{g}/\text{cm}^2$ of subject-specific measured palmar surface area is summarized in Tables 6 for vinyl flooring surfaces and Table 7 for carpet flooring surfaces. The percent transferability from the surface to the dressing sponges is also summarized in the tables. The dressing sponge residue data did not require correction for field fortification recoveries.

Bare Hand - Vinyl Flooring: The mean residue transferred from treated vinyl flooring sections to the bare hand was $0.168 \pm 0.059 \text{ } \mu\text{g}/\text{cm}^2$ for PER and $0.105 \pm 0.035 \text{ } \mu\text{g}/\text{cm}^2$. This represented a mean transferability of 3.27% for PER and 2.21% for PBO. Calculations made using Versar's corrected deposition value for PBO on alpha cellulose deposition coupons yielded a mean transferability of 1.92% for PBO residues.

Bare Hand - Carpet Flooring: Residues measured on bare hand press dressing sponges representing residues transferred from carpet flooring averaged $0.099 \pm 0.036 \mu\text{g}/\text{cm}^2$ for PER and $0.107 \pm 0.043 \mu\text{g}/\text{cm}^2$ for PBO. Approximately 1.98% of PER residues and 2.39% of PBO residues were transferred to bare hands from the carpet flooring. Calculations made using Versar's corrected deposition value for PBO on alpha cellulose deposition coupons yielded a percent transferability of 2.08% for PBO residues.

D. Cotton Percale - Indoor Roller Sample

Residue levels (μg) for each sample were divided by the total surface area covered by the roller to determine residue in $\mu\text{g}/\text{cm}^2$. The surface area covered by the roller was 30.48 cm x 91.44 cm yielding a total surface area of 2,787 cm^2 . Residue data are summarized in Table 8.

Percal - Vinyl Flooring: Residues found on percale samples generated from the indoor roller sampling on vinyl treated flooring surface demonstrated PER residues averaging $0.066 \pm 0.030 \mu\text{g}/\text{cm}^2$. This equated to a calculated mean transferability of 1.45%. PBO residues sampled under the same circumstances averaged $0.022 \pm 0.005 \mu\text{g}/\text{cm}^2$ with a mean transferability of 0.57%. Versar corrected the achieved PBO deposition rate values for an 87% field fortification found on the alpha cellulose deposition coupons. The corrected percent transferability of PBO residue was 0.50% for treated vinyl surfaces.

Percal - Carpet Flooring: For carpet treated flooring surfaces using the indoor roller method, PER and PBO residues measured $0.202 \pm 0.022 \mu\text{g}/\text{cm}^2$ and $0.170 \pm 0.026 \mu\text{g}/\text{cm}^2$, respectively on the percale cloth. Mean transferability was 4.37% for PER and 4.13% for PBO. Versar corrected PBO deposition rate values for an 87% field fortification value on alpha cellulose deposition coupons and calculated the % transferability of PBO residue onto cotton percale 3.59%.

VI. CONCLUSION

In this study, the target deposition rate for PER and PBO was the same (i.e., $3.96 \mu\text{g}/\text{cm}^2$). After contact with carpet treated samples, the PER and PBO residues were transferred onto sample matrices after sampling with a hand press and an indoor roller at a similar rate. The percentage of PER and PBO residue transferred to percale was higher than the percent transferred to the bare or gloved hand. The roller method of carpet sampling appears to collect a higher percentage of the PER and PBO residue than does the bare or gloved hand press. However, for vinyl treated flooring sampling, the bare hand appears to have higher levels of residue transferred per surface area than the percale or the gloved hand samples. The PER residue transferred from treated vinyl flooring surfaces to the sample matrices examined in this study were higher than the percentage of PBO residue transferred. PBO residues transferred from treated carpet to either percale (roller sampling), or cotton gloves or bare hands (hand press sampling) were more than PBO residues transferred from treated vinyl flooring. The same is true for PER residues, except that for the bare hand, the measured PER residues transferred from vinyl treated flooring were higher than the residues transferred from carpet treated flooring.

Table 9 summarizes the mean percent transferability of PER and PBO residue from treated vinyl and carpet flooring sections to the indoor roller percale cloth, and to bare and gloved hands. The results suggest that after contact with vinyl treated flooring surfaces, the percent of PER transferred to percale, and gloved or bare hands is always higher than the percent of PBO residue transferred. Also for vinyl surfaces, the percent of PER and PBO transferred to the bare hand was higher than the percent transferred to the gloved hand or to percale. The percentage of deposited PER and PBO residue transferred from vinyl treated flooring to percale and gloved hands was lower than the percentages observed after contact with carpet treated flooring.

LIMITATIONS OF THE STUDY:

The protocol provided with the study along with OPPTS Series 875 Part B, Guideline 875.2300: Indoor Surface Residue Dissipation, Postapplication and Part C Guidelines were used to review the study. Overall, the majority of

the procedures performed and the quality of the data generated in this study conformed to the criteria set forth in the protocol and guidelines. However, certain issues of concern were noted:

- A specific application rate was not provided in the Study Report. Application was based on a target deposition rate determined in another study.
- The test product was not identified and a label was not provided.
- Calibration procedures for the application equipment were not provided in the Study Report.
- The study author did not correct the alpha cellulose deposition residue data for the field fortification recoveries of PBO, which were below 90%.

Table 6. Summary of PER and PBO Hand Press Results on Vinyl Flooring															
Treated Surface	Subject	Hand	Measured Residue ($\mu\text{g}/\text{sample}$)		Palmar Hand Surface (cm^2) ^a	Measured Residue ($\mu\text{g}/\text{cm}^2$)		Overall Average ($\mu\text{g}/\text{cm}^2$)		% Transfer ^a			Average (% Transfer)		
			PER	PBO		PER	PBO	PER	PBO	PER	PBO	Corrected PBO	PER	PBO	Corrected PBO
Bare Hand Vinyl Floor	1	Right	10.6	6.57	79.5	0.133	0.083	0.168 \pm 0.059	0.105 \pm 0.035	2.59	1.75	1.52	3.27	2.21	1.92
	1	Left	14.5	8.20	88.3	0.164	0.093			3.20	1.96	1.70			
	2	Right	20.8	12.9	82.4	0.252	0.157			4.91	3.31	2.88			
	2	Left	16.2	10.4	85.6	0.189	0.121			3.68	2.55	2.22			
	3	Right	12.0	7.6	76.8	0.156	0.099			3.04	2.08	1.81			
	3	Left	5.16	3.36	82.2	0.063	0.041			1.23	0.86	0.75			
	4	Right	5.98	4.29	65.5	0.091	0.066			1.77	1.39	1.21			
	4	Left	13.1	8.55	66.8	0.196	0.128			3.82	2.69	2.34			
	5	Right	11.4	7.00	57.0	0.200	0.123			3.90	2.59	2.25			
	5	Left	14.6	8.68	62.8	0.232	0.138			4.52	2.91	2.53			
Cotton Glove Vinyl Floor	1	Right	5.36	3.67	79.5	0.067	0.046	0.041 \pm 0.02	0.021 \pm 0.014	1.31	0.97	0.84	0.81	0.45	0.39
	1	Left	0.814	0.28	88.3	0.01	0.003			0.18	0.07	0.06			
	2	Right	1.66	0.81	82.4	0.02	0.010			0.39	0.21	0.18			
	2	Left	3.27	1.50	85.6	0.038	0.018			0.74	0.37	0.33			
	3	Right	2.78	1.26	76.8	0.036	0.016			0.71	0.35	0.29			
	3	Left	6.75	3.40	82.2	0.081	0.041			1.60	0.87	0.75			
	4	Right	2.44	1.06	65.5	0.037	0.016			0.73	0.34	0.29			
	4	Left	1.74	0.62	66.8	0.026	0.009			0.51	0.19	0.17			
	5	Right	2.53	1.67	57.0	0.044	0.029			0.87	0.62	0.53			
	5	Left	3.34	1.60	62.8	0.053	0.025			1.04	0.54	0.46			

a Calculated as the ratio of the amount of residue present on the sample (dressing sponge or glove) divided by the average residue found on the alpha cellulose deposition coupons ($5.13 \mu\text{g}/\text{cm}^2$ for PER and $4.75 \mu\text{g}/\text{cm}^2$ for PBO). The PBO residue value on the alpha cellulose deposition coupon was corrected to 5.46 based on field fortification recovery.

Table 7. Summary of PER and PBO Hand Press Results on Carpet Flooring															
Treated Surface	Subject	Hand	Measured Residue (µg/sample)		Palmar Hand Surface (cm ²) ^a	Measured Residue (µg/cm ²)		Overall Average (µg/cm ²)		% Transfer ^a			Average (% Transfer)		
			PER	PBO		PER	PBO	PER	PBO	PER	PBO	Corrected PBO	PER	PBO	Corrected PBO
Bare Hand Vinyl Floor	1	Right	6.72	6.82	79.5	0.085	0.086	0.099	0.107	1.69	1.91	1.66	1.98	2.39	2.08
	1	Left	13.8	14.2	88.3	0.156	0.161	±	±	3.13	3.58	3.12			
	2	Right	7.74	7.56	82.4	0.094	0.092	0.036	0.043	1.88	2.04	1.78			
	2	Left	4.17	4.14	85.6	0.049	0.048			0.97	1.08	0.94			
	3	Right	7.11	7.38	76.8	0.093	0.096			1.85	2.14	1.86			
	3	Left	5.98	6.58	82.2	0.073	0.080			1.45	1.78	1.55			
	4	Right	5.17	5.36	65.5	0.079	0.081			1.58	1.82	1.59			
	4	Left	5.77	7.011	66.8	0.086	0.105			1.73	2.34	2.03			
	5	Right	6.54	7.28	57	0.115	0.128			2.29	2.84	2.48			
	5	Left	10.2	12.2	62.8	0.162	0.194			3.25	4.33	3.76			
Cotton Glove Vinyl Floor	1	Right	10.1	10.4	79.5	0.127	0.131	0.133	0.124	2.54	2.91	2.54	2.66	2.75	2.40
	1	Left	6.31	5.71	88.3	0.071	0.065	±	±	1.43	1.44	1.26			
	2	Right	10.6	13.2	82.4	0.129	0.160	0.032	0.031	2.57	3.57	3.10			
	2	Left	14.4	13.0	85.6	0.168	0.152			3.36	3.38	2.95			
	3	Right	11.0	10.0	76.8	0.143	0.130			2.86	2.90	2.52			
	3	Left	12.8	9.83	82.2	0.156	0.120			3.11	2.66	2.33			
	4	Right	9.64	9.58	65.5	0.147	0.146			2.94	3.26	2.83			
	4	Left	5.84	5.13	66.8	0.087	0.077			1.75	1.71	1.49			
	5	Right	7.87	6.76	57	0.138	0.119			2.76	2.64	2.31			
	5	Left	10.3	8.67	62.8	0.164	0.138			3.28	3.07	2.67			

^a Calculated as the ratio of the amount of residue present on the sample (dressing sponge or glove) divided by the average residue found on the alpha cellulose deposition coupons (5.00 µg/cm² for PER and 4.49 µg/cm² for PBO). The PBO residue value on the alpha cellulose deposition coupon was corrected to 5.16 based on field fortification recovery.

Table 8. Summary of PER and PBO Transferred from Vinyl and Carpet Flooring to Percal Using an Indoor Roller Method														
Treated Surface	Subject	Measured Residue ($\mu\text{g}/\text{sample}$)		Surface Area (cm^2)	Measured Residue ($\mu\text{g}/\text{cm}^2$)		Overall Average ($\mu\text{g}/\text{cm}^2$)		% Transfer ^a			Average (% Transfer)		
		PER	PBO		PER	PBO	PER	PBO	PER	PBO	Corrected PBO	PER	PBO	Corrected PBO
Percal Vinyl Flooring	1	169.7	47.3	2787	0.061	0.017	0.066	0.022	1.35	0.44	0.38	1.45	0.57	0.50
	2	296.9	74.9		0.107	0.027	±	±	2.37	0.70	0.61			
	3	100.1	53.5		0.036	0.019	0.030	0.005	0.80	0.49	0.44			
	4	161.0	73.4		0.058	0.026			1.29	0.67	0.58			
Percal Carpet Flooring	1	533.3	478.7		0.191	0.172	0.202	0.170	4.14	4.16	3.62	4.37	4.13	3.59
	2	651.6	576.4		0.234	0.207	±	±	5.08	5.01	4.36			
	3	545.9	426.2		0.196	0.153	0.022	0.026	4.25	3.70	3.22			
	4	516.4	418.4		0.185	0.150			4.01	3.63	3.16			

^a Calculated as the ratio of the amount of residue present on the sample divided by the average residue found on the alpha cellulose deposition coupons ($4.51 \mu\text{g}/\text{cm}^2$ for PER on vinyl flooring and $4.61 \mu\text{g}/\text{cm}^2$ for carpet flooring. The PBO deposition rate was reported as $3.87 \mu\text{g}/\text{cm}^2$ for vinyl flooring and 4.13 for carpet flooring. The PBO residue value on the alpha cellulose deposition coupon was corrected to $4.45 \mu\text{g}/\text{cm}^2$ for vinyl and $4.75 \mu\text{g}/\text{cm}^2$ for carpet based on field fortification recovery.

Table 9. Percent Residue Transferability from Treated Vinyl and Carpet Flooring to Sample Matrices			
Study	% Transferability ^a		%Transferability
	PER	PBO	
Vinyl Roller	1.45	0.57	0.50
Vinyl Gloved Hand Press	0.81	0.45	0.39
Vinyl Bare Hand Press	3.27	2.21	1.92
Carpet Roller	4.37	4.13	3.59
Carpet Gloved Hand Press	2.66	2.75	2.40
Carpet Bare Hand Press	1.98	2.39	2.08

^a transferability is calculated as the ratio of the average amount of residue present on the sample divided by the average residue found on the matrix specific alpha cellulose deposition coupon.

^b Versar corrected PBO residue values on the alpha cellulose deposition coupons for a field fortification value of 87%. Corrected alpha cellulose coupon data is presented in Table 5.

APPENDIX A

Compliance Checklist for “*Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press*”

Compliance Checklist for "Measurement of Transfer of Permethrin and Piperonyl Butoxide Residues from Vinyl and Carpet Flooring Treated with a Fogger Formulation Following a Single Hand Press"

**GUIDELINE 875.2300
INDOOR SURFACE RESIDUE DISSIPATION
POSTAPPLICATION**

1. *The test substance must be the typical end use product of the active ingredient.* It is unclear if this criterion was met. The test product was an unidentified product and no label was provided.
2. *The production of metabolites, breakdown products, or the presence of contaminants of potential toxicologic concern, should be considered on a case-by-case basis.* This criterion does not appear to apply to this study.
3. *Indoor surface residue studies should be conducted under ambient conditions similar to those encountered during the intended use season, and should represent reasonable worst case conditions.* This criterion was met.
4. *Ambient conditions (i.e., temperature, barometric pressure, ventilation) should be monitored.* This criterion was mostly met. The target conditions were identified and apparently met, but monitoring data were not provided in the Study Report.
5. *The end use product should be applied by the application method recommended on the label. Information that verifies that the application equipment (e.g., sprayer) was properly calibrated should be included.* It is not certain if these criteria were met completely. Information was provided verifying the calibration of the application equipment. However, it is uncertain if the test product was applied by the application method recommended on the label because the label for the test product was not provided with the study.
6. *The application rate used in the study should be provided and should be the maximum rate specified on the label. However, monitoring following application at a typical application rate is more appropriate in certain cases.* This criterion was not met. Application was based on a target deposition rate, determined in another study.
7. *If multiple applications are made, the minimum allowable interval between applications should be used.* This criterion does not apply to this study. There was only one application.
8. *Indoor surface residue (ISR) data should be collected from several different types of media (e.g., carpeting, hard surface flooring, counter tops, or other relevant materials).* This criterion was met. Indoor surface residues were collected from vinyl and carpet flooring.
9. *Sampling should be sufficient to characterize the dissipation mechanisms of the compound (e.g., three half-lives or 72 hours after application, unless the compound has been found to fully dissipate in less time; for more persistent pesticides, longer sampling periods may be necessary). Sampling intervals may be relatively short in the beginning and lengthen as the study progresses. Background samples should be collected before application of the test substance occurs.* This criterion does not apply to this study.
10. *Triplicate, randomly collected samples should be collected at each sampling interval for each surface type.* This criterion was met. For vinyl flooring and for carpet flooring analysis, 10 bare hand press samples and 10 gloved hand press samples as well as 4 indoor roller percale samples were collected for both carpet and vinyl flooring.
11. *Samples should be collected using a suitable methodology (e.g., California Cloth Roller, Polyurethane Roller, Drag Sled, Coupons, Wipe Samples, Hand Press, vacuum cleaners for dust and debris, etc.) for indoor surfaces.* This criterion was met. Samples were collected using appropriate methodology.
12. *Surface sampling should be conducted in conjunction with air sampling. Enough duplicate air samples should be taken in a room to establish a dissipation curve.* This criterion was not met.
13. *Samples should be stored in a manner that will minimize deterioration and loss of analytes between collection and analysis. Information on storage stability should be provided.* This criterion was met.

14. *Validated analytical methods of sufficient sensitivity are needed. Information on method efficiency (residue recovery), and limit of quantitation (LOQ) should be provided.* This criterion was met.

15. *Information on recovery samples must be included in the study report. A complete set of field recoveries should consist of at least one blank control sample and three or more each of a low-level and high-level fortification. These fortifications should be in the range of anticipated residue levels in the field study. These criteria were met.*

16. *Raw residue data must be corrected if appropriate recovery values are less than 90 percent.* This criterion was not met. Alpha cellulose coupon residue data were not corrected for an overall average field fortification recovery of 87% for PBO.

17. *Indoor surface residues should be reported as mg per m² or cm² of surface sampled. Distributional data should be reported, to the extent possible.* These criteria were met.

18. *Reported residue dissipation data in conjunction with toxicity data should be sufficient to support the determination of a reentry interval.* This criterion does not apply to this study.